

than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of an MA organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(4) Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with, the MA organization.

(6) Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

Related entity means any entity that is related to the MA organization by common ownership or control and—

(1) Performs some of the MA organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than \$2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of "business transaction" that, during any fiscal year of the MA organization, have a total value that exceeds \$25,000 or 5 percent of the MA organization's total operating expenses, whichever is less.

[65 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000; 70 FR 4736, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a

particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting a Notice of Intent To Apply will not form the basis of any action taken against the organization by CMS.

(c) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract; or

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part.

(d) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(e) *Resubmittal of application.* An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(f) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010]

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* If an MA organization fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) *Notice of determination.* Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, CMS gives the contract applicant notice of intent to deny the application for an MA contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the intent to deny notice, the contract applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as an MA organization or has not provided enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010]

§ 422.503 General provisions.

(a) *Basic rule.* In order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and